DEC 11 2000

K003143

Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

1. **Submitter's name, address, telephone number, contact person, and data summary prepared:**

   a. Millennium Biomedical Inc.
   360 East Bonita Avenue
   Pomona, California 91767
   Phone: (909)-621-7646
   Fax: (909)-621-7556

   b. Contact Person: Jerry Kaeni
   President

   c. Date Summary Prepared: September 15, 2000

2. **Name of device, including trade name and classification name:**

   a. Trade/Proprietary Name: MB 101 Millennium Blades

   b. Classification Name: Keratome, AC-Powered, and/or Blades

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Company	Device	510(k) No.	Dare Cleared
Moria	Moria LSK Blade	K970377	08/25/1998

4. **A description of the device that is the subject of the 510(k), including explanation of how device function, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

   The MB 101 Millennium Blade is a replacement blade designed to be used with the Moria LSK Microkeratome. The MB 101 Millennium Blade is a single-use only, disposable device. The Blade material is similar to that used in predicate devices (stainless steel).

5. **A statement of intended use:**

   The MB 101 Millennium blade is intended to be used as a replacement blade for the Moria LSK Microkeratome.

6. **A statement of how the technological characteristics of the device compare to those of the predicate or legally marketed devices:**

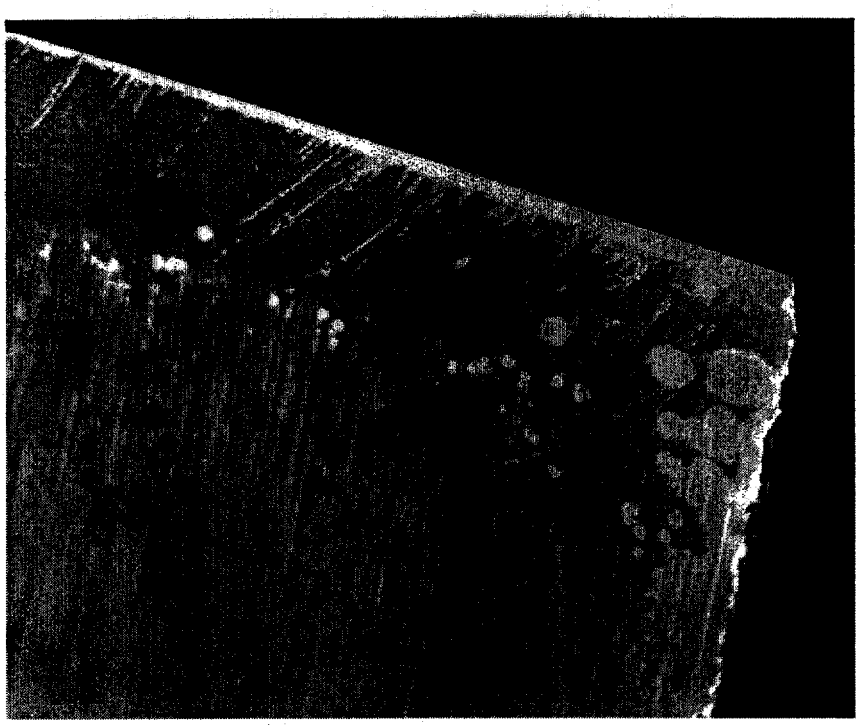
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE

CHARACTERISTICS	MORIA LSK BLADE (PREDICATE DEVICE)	MBI MB 101 MILLENNIUM BLADE
Intended Use	Indicated for use with the Moria LSK Microkeratome by surgeons to cut cornea in the form of a hinged flap in LASIK refractive surgery procedures.	Indicated for use as a replacement blade for the Moria LSK Microkeratome.
Operating Principle	The blade is held in the keratome head and oscillates by means of the turbine. The keratome head adapts to the turbine by means of a threaded part. The turbine motor is gas powered.	The blade is held in the keratome head and oscillates by means of the turbine. The keratome head adapts to the turbine by means of a threaded part. The turbine motor is gas powered.
Blade Design	Single edge blade with the plastic blade holder	Single edge blade with the plastic blade holder
Blade Hardness	52 Rockwell C	52 Rockwell C
Sterilization Method	Cobalt 60 radiation	Cobalt 60 radiation
Blade Material	Stainless steel	Stainless steel
Blade Holder Material	Delrin	Delrin
Patient Contact Portion of Device	Blade cutting edge	Blade cutting edge

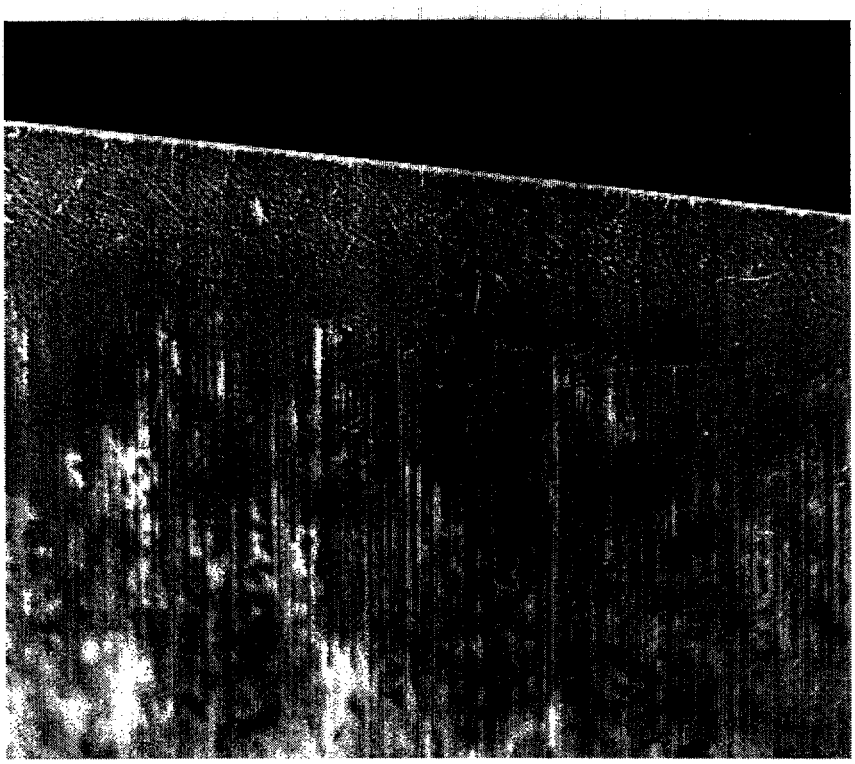
DIMENSIONAL EQUIVALENCY CHART

ATTRIBUTE	MORIA LSK BLADE (PREDICATE DEVICE) MEASURED	MB 101 MILLENNIUM BLADE
Length	0.49320	0.493"+0.002" -0.003
Width	0.3156	0.316" ± 0.001"
Thickness	0.1020	0.010" ± 0.0003"
Bevel	13°	13°
Mounting hole length	0.2810	0.2800" ± 0.0010"
Mounting hole width	0.0861	0.0860" ± 0.0010"
Sharpness verification	Inspected at 100X by Scanning Electron Microscope	• Inspected at 100X by Scanning Electron Microscope • Clinically tested and verified in China and Brazil

SHARP EDGE QUALITY COMPARISION

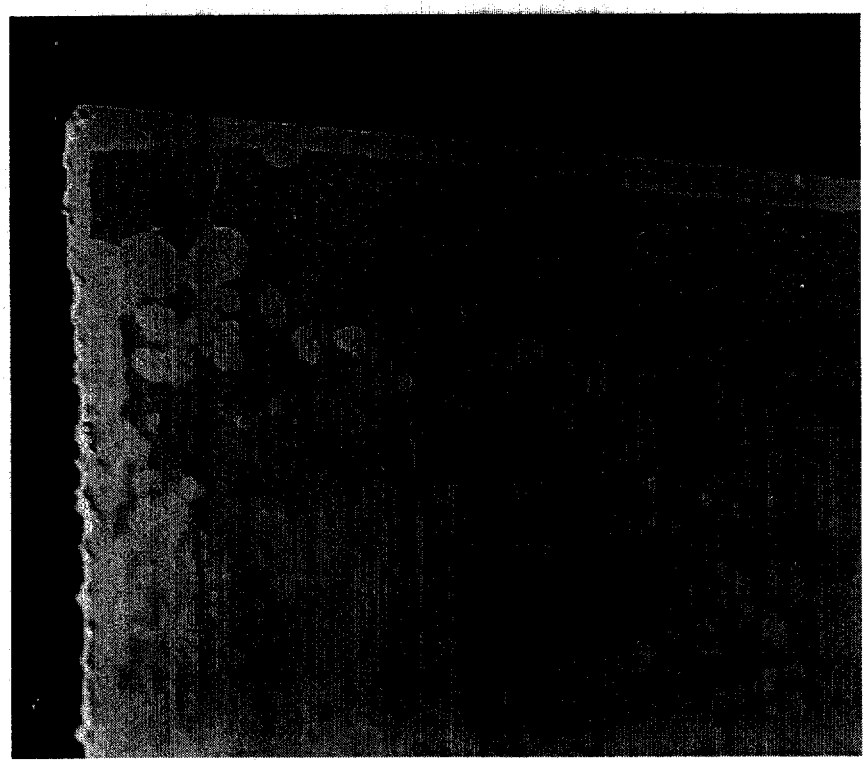


Moria SLK Blade, Right Edge at 97X



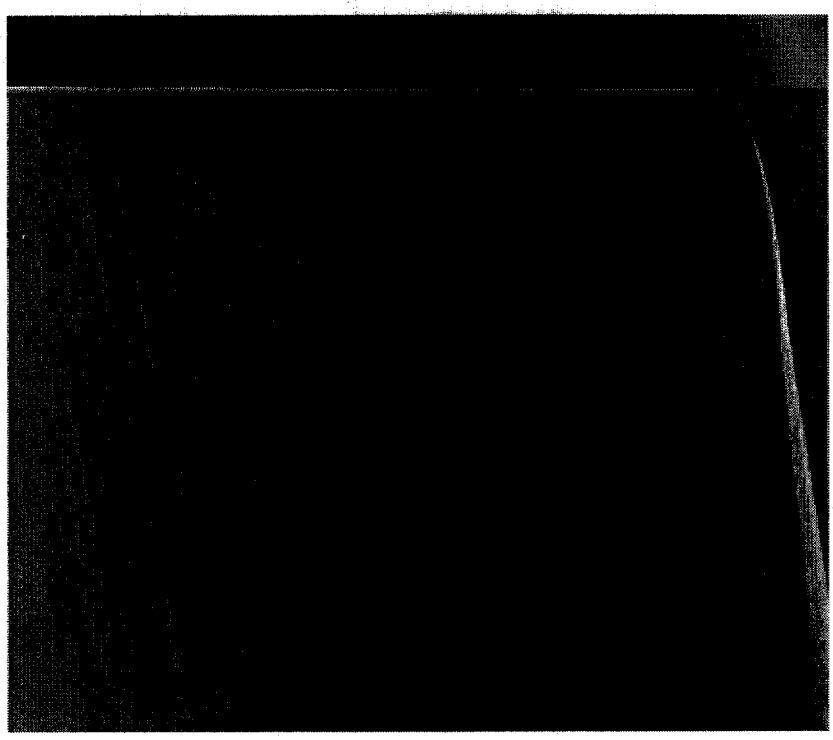
Moria LSK Blade, Center Edge at 101X

SEM Micrographs of Moria LSK Microkeratome Blade (PREDICATE DEVICE)

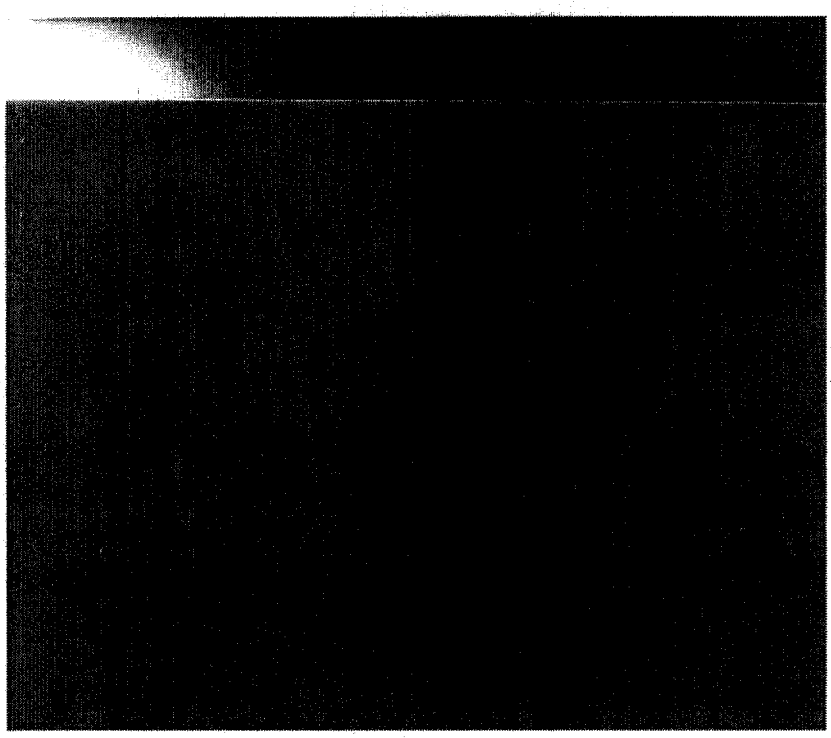


Moria LSK Blade, Left Edge at 104X

SEM Micrographs of Moria LSK Microkeratome Blade (PREDICATE DEVICE)

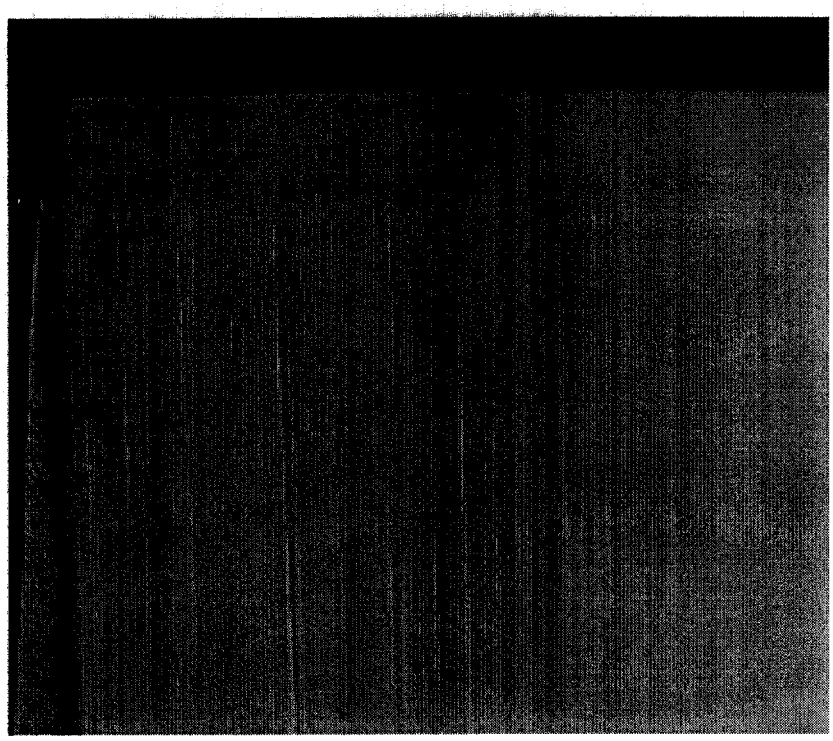


MBI Model MB101 Blade, Right Edge at 100X



MBI Model MB101Blade, Center Edge at 100X

SEM Micrographs of the MB 101 Blade manufactured by MBI



MBI Model MB101, Left Edge at 100X

SEM Micrographs of the MB 101 Blade manufactured by MBI

7. Brief summary of clinical tests and results

The performance of the MB 101 Millennium Blades was found to be acceptable by positive feedback from the market field study conducted in China and Brazil. The blades met the intended use and there were no adverse events reported when used according to the Moria LSK microkeratome manufacturers' instructions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

Mr. Jerry Kaeni
President and CEO
Millenium Biomedical, Inc.
360 E. Bonita Avenue
Pomona, CA 91767

Re: K003143
Trade Name: MB 101 Millennium Blades
Regulatory Class: I
Product Code: 86 HNO
Regulation: 886.4370
Dated: October 5, 2000
Received: October 10, 2000

Dear Mr. Walls:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K003143

Device Name: MB 101 Millennium Blade

Indications for Use:

The MB 101 Millennium blade is intended to be used as a replacement blade for the Moria LSK Microkeratome.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jan C Callaway

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003143

Prescription Use x **OR** **Over-The-Counter Use** _____

(Per 21 CFR 801.109)